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APPLICATION NO. 09/040,101	FILING DATE 03/17/99	FIRST NAMED INVENTOR KORNELITH	ATTORNEY DOCKET NO. 2509-980383
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EXAMINER GITUMER, R

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 14

Serial Number: 09/040,161
Filing Date: March 17, 1998
Appellant(s): Kornblith

Barbara Johnson
For Appellant

EXAMINER'S ANSWER

This is in response to Appellant's brief on appeal filed May 21, 1999.

(1) Real Party in Interest

5 A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

10 A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

15 This appeal involves claims 13-20.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

20 The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 13-20 stand or fall together.

(8) Claims Appealed

5 The copy of the appealed claims contained in the Appendix to the brief is mostly correct in the single copy provided, where ~~the~~compromise~~ed~~ may be intended to be ~~the~~comprise~~ed~~.

(9) Prior Art of Record

The rejections of record do not rely on any prior art.

10 **(10) New Prior Art**

No new prior art has been applied in this examiner's answer.

(11) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

15

Claims 13-20 stand rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The feature of the size of the particulates is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

20

On page 5 lines 15-16 of the present specification, "Preferably but not necessarily, the tumor particulates each measure 1 mm³." It would appear the claimed invention would not

work unless the particulates were of a certain size and the specification teaches only this one size.

Claims 13-20 stand rejected under 35 U.S.C. 112, first
5 paragraph, because the specification, while being enabling for
particles of a specific size, does not reasonably provide
enablement for particles of any size. The specification does not
enable any person skilled in the art to which it pertains, or
with which it is most nearly connected, to make and use the
10 invention commensurate in scope with these claims.

In claim 13 and all occurrences, the terms "cohesive
multicellular particulates" lack enablement as it would require
one of ordinary skill in this art undue experimentation to
determine which size would work in the instant invention.

15 "Cohesive multicellular particulates" reads on an entire
organ to two cells, neither of which are likely to work in the
claimed invention. The addition to the claims of "having smooth
cut edges" does not in any fashion distinguish the size of the
particulates. And referring to minced tumor tissue, although
20 indefinite regarding size, refers to very small samples.

Note this examiner was employed in a pathology lab where
most of the samples he received were severed heads, either
complete or portions thereof. Virtually all of the samples had
at least one smooth cut edge at the neck where the specimen was
25 prepared and most of the samples had some region of minced

tissue, generally where an injury occurred such as a bullet exit wound. Most of the heads weighed 10-12 pounds, were cohesive multicellular particulates, had smooth cut edges and had minced tissue. And possibly some of the heads had tumor tissue which would then read on the presently claimed samples directly.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large number of sizes claimed.

2. Amount of direction or guidance presented is insufficient to predict which sizes encompassed by the claims would work.

3. Presence of working examples are only for a single size and extension to other sizes has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most sizes are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of sizes.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 13-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 13, "cohesive multicellular particulates" is not understood as so what the specimen is separated into. Note the expression reads on no separating to forming two cell particulates.

(12) New Ground of Rejection

10 This examiner's answer does not contain any new ground of rejection.

(13) Response to argument

15 Appellant argues that the sample size is not a critical feature and the sample would have to be of an appropriate size to culture. The purpose of culturing the cells is to assess a biopsy sample to avoid gross surgical intervention. The size limitations are readily deduced according to the teachings of the specification. No experimentation is required to practice the invention because a sample size is specified in the disclosure.

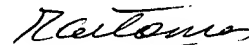
20 It is the examiner's position that in view of the prosecution of issued patent 5,728,541 for which a Terminal Disclaimer has been filed in the present application, the size of the sample is critical and this single feature is the sole
25 difference between the claims in the applications.

The claims have no limitations directed to the size of the cohesive multicellular particulates and many sized samples can be cultured. When culturing environmental samples, for example, huge samples are routinely employed for culturing. The purpose of culturing the cells is unrelated to the size of the sample which is cultured.

Regarding the single size of the sample disclosed in the specification which may be cultured, Appellant is reminded that the invention is the subject matter defined by the claims, and the limitations of the specification are not read into the claims where no express statement of that limitation is included in the claims, see *In re Priest*, 199 USPQ 11.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



RALPH GITOMER
PRIMARY EXAMINER
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